# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL NO. 1456 Civil Action No. 01-12257-PBS

THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339

Judge Patti B. Saris

# TRACK ONE DEFENDANTS' SUR-REPLY IN OPPOSITION TO CLASS CERTIFICATION

[REDACTED VERSION FOR PUBLIC FILING]

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#### INTRODUCTION

Plaintiffs have redefined their classes again and now seek to certify classes of all individuals and entities whose payments for (1) pharmacy-dispensed or (2) physician-administered prescription drugs were based on AWPs. The effect of this tactic is to merge into the physician-administrated class those who made payments under Medicare and those persons or entities who paid for physician-administered drugs outside of Medicare.

It is evident from the record (including the Court's tutorial sessions) that the alleged scheme to fraudulently inflate AWPs did not cause injury to all members of either class. With respect to the pharmacy-dispensed class, some class members had sufficient knowledge about the nature of AWP, others had sufficient leverage in negotiating the prices they paid, and others who utilize PBMs benefitted from competition among those entities and their negotiating leverage with defendants. For any one or a combination of these reasons, the alleged AWP scheme did not injure every payor whose payments were based on AWP. Class certification for pharmacy-dispensed drugs, therefore, is inappropriate because the task of separating the injured payors from the uninjured payors will require tens of thousands of individual determinations that will swamp any common issues.

Plaintiffs try to overcome this obstacle to class certification by advancing a novel theory of liability. They now assert that AWPs are a "signal" for actual transaction prices and that defendants' alleged inflation of AWPs caused the difference between AWP and actual prices to exceed the class members' expectations. Because the task of determining each class member's "expectation" would obviously require a multitude of individual inquiries, plaintiffs propose to "average" the supposed "expectations" among class members. But averaging is no substitute for the unavoidable task of assessing each class member's "expectation" in order to prove injury as well as the falsity of an alleged AWP representation.

The proposed physician-administered class is equally inappropriate. The Dyckman study, on which plaintiffs so heavily rely, acknowledges that the payors in this class know that physicians acquire drugs for prices substantially below AWP. Consistent with those findings,

many payors testified that they understood AWP did not bear a predictable relationship to physicians' acquisition costs and, in fact, many purchased physician-administered drugs at varying discounts well below AWP. Those payors nevertheless use AWP as a reimbursement benchmark. In some cases, private payors reimburse at or above AWP as a way of making up for undercompensating physicians for the services they provide (just as the Medicare program did for many years). Whether these payors were injured by the alleged AWP scheme can only be determined through individual inquiry.

The proposed physician-administered class is improper for two additional reasons. First, plaintiffs' claims with respect to this class are brought exclusively under state consumer statutes and would require the Court to apply the laws of every state. This is impractical in light of material differences in each state's law. Second, plaintiffs' proposed class representatives are not typical of the physician-administered class.

Finally, plaintiffs have failed to devise an acceptable trial plan for either the pharmacy-dispensed or physician-administered classes. Instead, they proffer a vague trial scheme that would ride rough-shod over defendants' important substantive rights. Plaintiffs' defense of their trial plan rests on the assertion that causation need not be determined on an individual basis, but that is plainly false. Furthermore, plaintiffs' glib assertions that a case of this magnitude – with a proposed nationwide class of over 200 million persons and 10,000 corporate entities asserting novel claims against five defendant groups who manufacture 136 different products – could be heard by a single jury, applying the laws of over 50 jurisdictions, are not credible.

#### **ARGUMENT**

# I. PLAINTIFFS' PROPOSED CLASSES DO NOT SATISFY THE PREDOMINANCE REQUIREMENT OF RULE 23(B)(3)

All of plaintiffs' fraud-based claims require proof of injury proximately caused by a false statement. *See Poulos v. Caesars World, Inc.*, 379 F.3d 654, 664 (9th Cir. 2004). Where, as here, proof of these elements of liability requires individualized inquiry, class certification is not

appropriate. See, e.g., Poulos, 379 F.3d at 664-66; Markarian v. Connecticut Mut. Life Ins. Co., 202 F.R.D. 60, 69 (D. Mass. 2001).

#### A. Individual Issues of Knowledge Preclude Class Certification

The impropriety of plaintiffs' new proposed classes follows from the plaintiffs' new theory of their case. Plaintiffs have abandoned their initial contention that manufacturers' AWPs must conform to the plain meaning of that term – that they must correspond to an average of actual transaction prices. Plaintiffs now contend that (1) AWP was a "signal" for actual acquisition costs, (2) members of their putative classes had "expectations" about the relationships between AWPs and pharmacy and physician costs for the acquisition of drugs, and (3) the spread between AWPs and actual acquisition costs exceeded those expectations.

There are many reasons why this theory of liability cannot be proven on a class basis, but one is sufficient to preclude certification: class members differ widely in their "expectations" as to the relationship between AWP and acquisition costs. For example, some putative class members understood fully the existence and significance of the spread between published AWPs and the acquisition costs of pharmacies and physicians.<sup>2</sup> Others purchased drugs themselves and, therefore, had first-hand knowledge of the acquisition cost for drugs and were familiar with the extent and variability of the spread.<sup>3</sup> Putative class members have even stated that they were

<sup>&</sup>lt;sup>1</sup> See Hartman Rebuttal Decl. ¶ 25(d) ("[a]nyone who knows this industry knows that almost no one pays AWP and that AWP diverges from transaction prices"). The expert and tutorial submissions of both sides have clearly established that with respect to brand drugs AWP is generally derived by multiplying the manufacturer's undiscounted list price (generally "wholesale acquisition cost" or WAC) by a mark-up factor of typically 1.2 or 1.25. See Written Tutorial of Meredith Rosenthal at 11; Schondelmeyer, Abt Associates, Inc., Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices: Final Report (hereinafter "Medicaid and Medicare Drug Pricing") (June 21, 2004) at 15, 17; Gregory K. Bell & Fiona Scott Morton, Script for DVD Tutorial Submission of the Track One Defendants (hereinafter "Defs.' Tutorial Script") (Dec. 3, 2004) at 2-3; Init. Young Decl. ¶¶ 46-47.

<sup>&</sup>lt;sup>2</sup> See, e.g., ; Beaderstadt (John Deere) Sept. 17, 2004 Dep. Tr. 80-81; Sidwell (John Deere) Sept. 17, 2004 Dep. Tr. 38-40.

<sup>&</sup>lt;sup>3</sup> See, e.g., REDACTED

Kenney (Harvard Pilgrim) Sept. 20, 2004 Dep. Tr. 14-15, 67; Sidwell (John Deere) Sept. 17, 2004 Dep. Tr. 41-43.

not defrauded by published AWPs and would have paid the same prices even if they used a different pricing benchmark than AWP.<sup>4</sup> Many class members used benefit consultants, third-party administrators, negotiating groups or other sophisticated intermediaries in the course of their negotiations with PBMs and providers.<sup>5</sup> For these reasons, those class members knew that a substantial spread sometimes existed between AWPs and acquisition costs.<sup>6</sup>

Further, plaintiffs' industry expert, Dr. Stephen W. Schondelmeyer, states that AWP is a fairly reliable predictor of *one kind of price* – namely, the predictably lower acquisition cost of retail pharmacies for brand name drugs that are under patent and do not face competition from therapeutic alternatives. (Schondelmeyer, *Medicaid and Medicare Drug Pricing* at 17.) Finally, some putative class members, including several named plaintiffs, did not consider AWP a signal for *any* price. (Young Sur-Rebuttal Decl. Part III A and B and materials cited therein.).

If reported AWPs were consistent with a class member's expectations, then the "signal" was neither false nor could it have caused injury. The only way to determine what each class member's expectation was is to question them, but that approach plainly fails the predominance test. Plaintiffs propose that their expert, Dr. Hartman, can smooth out the varying expectations of the class members by averaging them to arrive at an "expectation yardstick." But averaging is a notoriously inadequate guide to making important decisions. As has been observed, "Never try to walk across a river just because it has an average depth of four feet." Martin Friedman, in Robert I. Fitzhenry, ed., *Harper Book of Quotations*, HarperCollins, New York (1993).

Class members' knowledge about the spread between published AWPs and pharmacy and physician acquisition costs is critical to this case because "[k]nowledge of the truth defeats a

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<sup>\*\*</sup>REDACTED , Farias (Harvard Pilgrim) Oct. 20, 2004 Dep. Tr. 120-21.

<sup>&</sup>lt;sup>5</sup> See, e.g., REDACTED

<sup>&</sup>lt;sup>6</sup> See, e.g., Pfankuch (Blue Cross Blue Shield of Illinois) Sept. 14, 2004 Dep. Tr. 50;

claim of fraud because it eliminates the deceit as the 'but for' cause of the damages." Sandwich Chef of Texas, Inc. v. Reliance Nat'l Indem. Ins. Co., 319 F.3d 205, 218-19 (5th Cir. 2003); see also Poulos, 379 F.3d at 665 (upholding denial of class certification because plaintiffs' knowledge, motivations and expectations bore heavily on the causation analysis). For example, in Markarian v. Connecticut Mut. Life Ins. Co., Judge Wolf refused to certify a class of individuals who had purchased insurance policies in thousands of face-to-face meetings. See Markarian, 202 F.R.D. at 68-69. "[T]he total mix of information made available to each purchaser was distinctive, if not unique, and the question of causation must be decided with regard to each purchaser in the context of the particular information that he or she received." Id. at 69. Similarly in this case, the varying levels of knowledge among class members about the relationship between AWP and acquisition cost will require the court to engage in individualized fact finding in order to determine whether defendants' published AWPs caused any injury to each class member. A proposed class raising such issues is not appropriate for class treatment. See, e.g., Zimmerman v. Bell, 800 F.2d 386, 390 (4th Cir. 1986).

Moreover, plaintiffs' new fraud theory based on "expectations" requires individualized proof of the expectation of each class member to attempt to demonstrate the falsity of an alleged AWP representation. *See Lum v. Bank of America*, 361 F.3d 217, 226 (3d Cir. 2004) (public's differing expectations of banking term "prime rate" precludes fraud claim that defendant bank omitted to disclose to certain borrowers availability of discounts below prime), *cert. denied*, 125 S.Ct. 271 (2004). Plaintiffs cannot have it both ways. They cannot pursue a fraud theory based on varying expectations and pursue that theory on a classwide basis.

### B. Variability In Payments Precludes Class Certification

The initial declaration supplied by defendants' expert, Dr. Eric M. Gaier, demonstrated significant variability in net reimbursement among third-party payors in the proposed classes, and in many instances, the pattern of reimbursement bears no systematic relationship to AWP. Using data obtained through discovery, Dr. Gaier explained that this variability was caused by a

variety of factors, including: (a) differing levels of knowledge among class members, (b) differing abilities by class members to leverage competition, and (c) trade-offs made during individualized negotiations with respect to the various components that constitute reimbursement contracts. (Init. Gaier Decl. at ¶¶ 47-59; see also Defs.' Tutorial Script at 44-50, 57-59.) As a result of those differences, Dr. Gaier concluded that whether or not a class member has been injured can only be determined by assessing the facts and circumstances surrounding each class member's individual transactions. (Init. Gaier Decl. at ¶ 10.)

In his rebuttal declaration, Dr. Hartman concedes that there is significant variation in reimbursement levels and that competition, knowledge and trade-offs can have an impact. (Hartman Rebuttal Decl. ¶¶ 45(c), 63, 72(b).) Dr. Hartman nevertheless concludes that all class members have been injured because, in the "but for world," AWPs would be lower. (*Id.* at ¶ 3(d).) Yet, Hartman fails to reconcile this new assertion with the multiple arrangements that effectively lower net reimbursements, the fact of cross-subsidization, or even his prior concession that it is possible that a substantial number of class members did not suffer any injury. (Init. Hartman Decl. ¶ 36; Hartman Oct. 7, 2004 & Oct. 8, 2004 Dep. Trs. 269-71, 287, 502-04, 513.)

Hartman's support for this revised view that all class members have been injured is two-fold. First, he asserts that many contracts use AWP as a benchmark. (Hartman Rebuttal. Decl. ¶¶ 19-36; Plfs.' Reply Mem. at 1, 4, 6.) That, of course, is beside the point. As defendants' tutorial demonstrated, many contracts reference AWP, but the net reimbursement is substantially below AWP and many include rebates as well as trade-offs among other contract terms. (Defs.' Tutorial Script at 5-11, 55-59; Gaier Sur-Rebuttal Decl. ¶¶ 31-35.) Second, Dr. Hartman asserts that

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Again, Hartman fails to reconcile this latest contention with

his earlier finding that

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More importantly, Dr. Hartman fails to consider the obvious alternative explanation for the range of discounts - i.e., if manufacturers sell brand name drugs to wholesalers for WAC; and if pharmacies acquire the drugs for WAC plus a small percentage mark-up; and the difference between WAC and AWP is REDACTED then the class member is going to have to reimburse at a higher rate than AWP minus REDACTED if the pharmacy is going to remain in business. (Schondelmeyer Decl. ¶¶ 63, 89.) Furthermore, Dr. Hartman's analysis repeatedly ignores the fact that class members and PBMs negotiate over rebates from manufacturers and, in many instances, class members share in the rebates - thus reducing their net reimbursement. (Defs.' Tutorial Script at 50-56; Gaier Sur-Rebuttal Decl. ¶ 29.) Finally, Hartman also ignores that the class members do not really pay AWP minus particular drug. Instead they pay AWP minus , minus the negotiated pass through of the manufacturer rebate, plus any administrative or dispensing fees. (Defs.' Tutorial Script at 5-11, 55-56.)8 Because all of these financial factors are inter-related moving parts from contract to contract (and are the subject of intense competition between and among pharmacies, PBMs and payors) (Defs.' Tutorial Script at 44-59), it is impossible to isolate AWP-based aspects of reimbursement from non-AWP-based aspects of reimbursement through common proof.

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<sup>8</sup> See also, Montana) Sept. 28, 2004 Dep. Tr. 51-52. REDACTED

Wong (Blue Cross Blue Shield of

<sup>&</sup>lt;sup>7</sup> This **REDACTED** does not exist in the physician-administered market.

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Proceeding on a class basis is not

feasible as it will require the Court to address on an individual basis the questions Hartman cannot answer.

#### C. The Diversity of the Contracts At Issue Precludes Class Certification

Because the contracts at issue are individually negotiated, class certification is inappropriate. For example, in *Robinson v. Texas Auto. Dealers Ass'n*, 387 F.3d 416 (5th Cir. 2004), plaintiffs asserted that Texas automobile dealers engaged in an antitrust conspiracy by charging the state's vehicle tax as a separate line item on each sales contract. The *Robinson* plaintiffs assumed that the tax artificially inflated the final purchase price for every class member. But the court of appeals noted that this assumption "defies the realities of the haggling" in the market place, *id.* at 423, and ruled that the case could not proceed as a class action because the trial court "would have to hear evidence regarding *each purported class member and his transaction*" and "[s]uch an individual examination would destroy any alleged predominance present in the proposed class." *Id.* at 424 (emphasis original). Like Judge Wolf's decision in *Markarian*, the *Robinson* case demonstrates that a class should not be certified here.

Similarly, in *Mulder v. PCS Health Systems Inc.*, 216 F.R.D. 307 (D.N.J. 2003), the plaintiff tried to certify a class of some 250,000 participants in approximately 1,250 health plans that had contracts with the defendant PBM. The plaintiff claimed that the PBM violated its fiduciary duty by, among other things, accepting payments from pharmaceutical manufacturers. The court refused to certify a class including the members of multiple plans because "significant variations" among the contracts between the PBM and the plans created individual issues with respect to the PBM's duties. *Id.* at 316.

In this case, the fact that class members' negotiations with PBMs involve an array of non-reimbursement rate dimensions would require this Court to engage in endless individualized inquiries. The particular "bundle" of services selected by a third-party payor will depend on its unique preferences, needs and circumstances. (Defs.' Tutorial Script at 42-44, 57-59.) As a

result, isolating a causal link between a single aspect of the contractual relationship – e.g., drug reimbursement formula – and defendants' alleged conduct would require contractually specific analysis. For example, in *Kennett Corp. v. Massachusetts Furniture & Piano Movers Ass'n, Inc.*, 101 F.R.D. 313 (D. Mass. 1984) – where Dr. Hartman appeared as an expert on class certification – the court denied certification in an antitrust case in light of the bundle of moving services that differed from mover to mover, and from customer to customer, and it was impossible to tell how each customer had been injured by the alleged misconduct. *Id.* at 316.

## II. ADDITIONAL FACTORS WEIGH AGAINST PLAINTIFFS' PROPOSED PHYSICIAN-ADMINISTERED CLASS

In addition to the foregoing, there are specific market factors that preclude certification of the physician-administered class. This proposed class also fails because of the diversity of the fifty state statutes plaintiffs invoke and the absence of adequate or typical class representatives.

### A. Physician-Administered Market Forces Preclude Class Certification

The market for physician-administered drugs outside Medicare Part B presents individual issues with respect to (1) competition among physicians and the ability of payors to leverage that competition; (2) the knowledge that payors have of the difference between AWPs and acquisition costs; and (3) trade-offs between reimbursement for drugs and reimbursement for services in the contracts between payors and physicians. In their reply, plaintiffs attempt to gloss over the differences between physician-administered drugs in the private sector and physician-administered drugs under Medicare Part B (Plaintiffs' Reply Mem. at 13-15), but the reality is that contractual negotiations for physician-administered drugs in the private sector raise individual issues that preclude class certification.

<sup>&</sup>lt;sup>9</sup> As set forth in the Sur-Rebuttal Declaration of Steven Young, contracts for reimbursement of physicianadministered drugs, which often do not even refer to AWP, are based on negotiations of an overall fee schedule designed to secure continued access to physician services.

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<sup>¶¶ 7-11, 29.</sup> Even where AWP is a component of the contracts, which would be difficult to ascertain, the market forces belie plaintiffs' inference of expectations from negotiated discounts off AWP.

To support their contention that common issues predominate with respect to physician-administered drugs in the private sector, plaintiffs rely on the "Dyckman Study" (Dyckman & Associates, Health Plan Payment for Physician Administered Drugs, Medicare Payment Advsory Commission (Aug. 2003)) which they claim "found that all plans reimbursed for such drugs based on AWP." (Plfs.' Reply Mem. at 2.) However, plaintiffs fail to note that the study included only a sampling of one type of insurer, and omit the study's finding that "[t]here is a general understanding among health plans that physicians purchase drugs at prices that are below 95% of AWP and, given that health plan prices are generally at or above this rate, the sale of drugs is a profit center for physicians." (Dyckman Study at 4.) The study also found: "Approximately half of the health plans planning to reduce drug prices will consider raising fees for drug administration codes." (Id.) The Dyckman Study thus acknowledges and reflects the interrelationship between reimbursement for drugs and reimbursement for services on the physician administered side (an interrelationship that has been well established under Medicare Part B).<sup>10</sup>

In many instances, payors' use of drug reimbursement to subsidize the reimbursement for services is shown by the payors' election to reimburse physicians at higher rates than pharmacies for the same drug. At least 20 of the approximately 35 physician-administered Track One drugs identified in the AMCC are "dual-channel" drugs sold in both markets. (Young Sur-Rebuttal Decl. at ¶¶ 26-28.) And, "[t]he factors that caused the health plans to provide enhanced reimbursement for physicians can be determined only based on an analysis of the negotiations between the health plan and the physicians." *Id.* at ¶ 28.

<sup>&</sup>lt;sup>10</sup> The recent reduction of Medicare reimbursement for physician-administered drugs to average sales price plus 6% has necessitated an increase in physician fees for some drugs. For example, CMS increased the monthly dispensing fee for albuterol from \$5 to \$57. (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005, 69 Fed. Reg. 66,236-01 (Nov. 15, 2004); see also Defs.' Tutorial Script at 36.)

These examples illustrate that some members of the putative class of payors for physician-administered drugs – virtually all of whom are also included in the putative class of payors for pharmacy-dispensed drug class – have knowledge and economic leverage to negotiate reimbursement rates for *both* categories of drugs. As in the market for pharmacy-dispensed drugs, the availability of these resources to members of the proposed physician-administered class varies so widely that the differences among class members overwhelm their similarities.

#### B. Variations in State Law Preclude Class Certification

Legal as well as factual variations preclude certification of the plaintiffs' proposed physician-administered class. The only claims asserted by plaintiffs with respect to physician-administered drugs (both privately reimbursed and Medicare Part B drugs) arise under state consumer protection statutes, which vary in numerous material respects. "To establish commonality of the applicable law, nationwide class action movants must creditably demonstrate, through an 'extensive analysis' of state law variances, 'that class certification does not present insuperable obstacles." Walsh v. Ford Motor Co., 807 F.2d 1000, 1017 (D.C. Cir. 1986). The superficial analysis offered by plaintiffs wholly fails to satisfy this burden, especially in light of the extensive review of relevant state law provided by the defendants.

#### 1. Plaintiffs Apply The Wrong Choice-Of-Law Rules

Plaintiffs attempt to limit the number of states whose laws will apply to this case by arguing that the Court should apply the law of the state where each defendant is headquartered. However, plaintiffs fail to address the First Circuit's recent decision in *Reicher v. Berkshire Life Ins. Co. of America*, 360 F.3d 1 (1st Cir. 2004), where the Court rejected the precise argument made by plaintiffs here. In *Reicher*, a Maryland plaintiff attempted to sue a Massachusetts insurance company for violations of Massachusetts' consumer protection statute. The court held that Maryland law applied because application of Massachusetts law would undermine legitimate

This, among other things, distinguishes this case from *In re Lupron Sales and Marketing Practices Litig.* before Judge Stearns, where there also was a federal RICO claim.

policy decisions made by Maryland regarding regulation of the transactions at issue. *Id.* at 5-6. So, too, here, nationwide application of a few states' laws would frustrate the objectives of the other states regarding regulation of consumer transactions within their borders.

Contrary to plaintiffs' mischaracterization of *In re Relafen Antitrust Litig.*, 221 F.R.D. 260 (D. Mass. 2004), Judge Young did precisely what Massachusetts' functional choice-of-law approach required: he determined which state had the more significant interest in the transactions at issue. Given the policies underlying state consumer protection statutes, he concluded that the law of the state where the purchases took place should be applied. *See id.* at 277-78. Judge Young's conclusion is consistent not only with *Reicher*, but with the decisions of numerous other courts applying similar interest-based approaches to choice-of-law in cases asserting statutory consumer fraud claims. (Init. Indiv. GSK Mem. 3 nn. 4-5).<sup>12</sup>

Plaintiffs' reply brief also does not address the constitutional limitations on choice-of-law in any meaningful way. Under plaintiffs' overly simplistic approach, constitutional considerations would focus solely on the defendant's contacts with the state. Neither *Shutts*, nor the Supreme Court's Commerce Clause decisions support such an approach. For example, in *Shutts*, although the defendant had a substantial presence in Kansas, the Court held that

<sup>&</sup>lt;sup>12</sup> Plaintiffs rely on Randle v. SpecTran, 129 F.R.D. 386 (D. Mass. 1988) and Grace v. Perception Tech. Corp., 128 F.R.D. 165 (D. Mass. 1989). Yet, unlike Judge Young's decision in Relafen, these courts lacked the benefit of more recent precedent regarding choice of law in general and as applied to nationwide class actions. As a result, the brief discussion of the issue in those cases focused almost exclusively on the defendants' contacts with Massachusetts and gave scant attention to the interests of the states where the transactions occurred. Reicher makes clear that such an approach is inappropriate.

The other cases relied upon by plaintiffs are also inapposite. The court in *In re Lutheran Brotherhood Variable Ins. Prods. Co. Sales Practice Litig.*, No. 99-MD-1309, 2003 U.S. Dist. LEXIS 12929 (D. Minn. July 22, 2003), concluded, incorrectly, that "the choice-of-law analysis is unnecessary." *See id.* at \*15. *In re Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231 (D. Del. 2002), is distinguishable because the court was certifying a class for settlement only. *See id.* at 250. At the same time, the court noted that the possible need to apply multiple state laws made the risk of decertification significant. *Id.* at 256. In *Simon v. Philip Morris, Inc.*, 124 F. Supp. 2d 46 (E.D.N.Y. 2000), the court's choice-of-law analysis was slanted to facilitate class certification. *See id.* at 77-78. That approach violates the principle that class certification does not change substantive law or constitutional constraints. *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 613 (1997); *Phillips Petroleum v. Shutts*, 472 U.S. 797, 820-21 (1985).

application of Kansas law to a nationwide class was unconstitutional. *See Shutts*, 472 U.S. at 819-20, 823. *Shutts* requires an aggregation of contacts based on an analysis of the claims asserted and the expectations of the parties. *See id.*; *see also Relafen*, 221 F.R.D. at 266-77. As we have demonstrated, that analysis points to the state where the transaction occurred. Moreover, plaintiffs fail to explain how this Court can, for example, constitutionally apply New York's consumer protection statute to a transaction that occurred in Texas and is not actionable under New York law. *See McLean v. Mut. Life Ins. Co. of N.Y.*, 295 F. Supp. 2d 140, 144-45 (D. Mass. 2003).

Plaintiffs also would have this Court ignore Commerce Clause limitations on the authority of one state to impose its policy choices on other states and regulate consumer transactions outside its borders. *See, e.g., BMW of N. America, Inc. v. Gore*, 517 U.S. 559, 571-73 (1996).

#### 2. Variations In States' Laws Are Numerous And Material

Defendants have provided this Court with a detailed analysis of the numerous material and outcome-determinative conflicts between state consumer protection statutes and conspiracy laws. (See Appendices A & B to Defs.' Opening Mem.; see also Init. Indiv. GSK Mem. at 3-6.) These differences include the statutory elements that must be proven, the burden of proof, standing, statute of limitations, damages, and, with respect to the conspiracy laws, the underlying tort of common law fraud. Instead of making a creditable showing of how such variations in state law can be managed, plaintiffs suggest only that the class can be subdivided between those states that require reliance and scienter and those that do not. Defendants have demonstrated that variations in state law are far more extensive than that. Indeed, numerous courts have held that variations in state consumer protection statutes preclude certification of nationwide classes. (See Init. Indiv. GSK Mem. 3 nn. 4-5, 6 nn. 27 & 30.)<sup>13</sup> Where state law variations are so extensive,

<sup>&</sup>lt;sup>13</sup> Plaintiffs attempt to distinguish the cases cited by defendants as product liability cases, but offer no valid reason why that should make a difference. In most of the cases cited by defendants, plaintiffs pursued a claim under state consumer protection laws, and the courts held that state law variations precluded certification of a nationwide

subclassing is no answer. See McBride v. Galaxy Carpet Mills, Inc., 920 F. Supp. 1278, 1284 (N.D. Ga. 1995).

Plaintiffs argue, in the alternative, that differences in state law are irrelevant because their claims will satisfy each state's law. But such an argument requires this Court to assume the outcome of this litigation in order to decide class certification. The variations in state law identified by the defendants are clearly material. A verdict cannot be obtained consistent with due process when the need to instruct the jury under the differing laws of over fifty jurisdictions would render their task impossible. See In re American. Med. Sys., Inc., 75 F.3d 1069, 1085 (6th Cir. 1996); Ilhardt v. A.O. Smith Corp., 168 F.R.D. 613, 620 (S.D. Ohio 1996).

## C. Plaintiffs Are Not Typical of and Cannot Adequately Represent the Proposed Physician Administered Class

As noted in defendants' opening memorandum, none of the named plaintiffs is a person who purchased a drug for personal consumption or household use. As a result, the named plaintiffs would not even have standing to pursue a claim under approximately half of the state consumer protection statutes (see Defs.' Opening Mem., Appendix A) and therefore, are not typical of the class they seek to represent.

Furthermore, none of the named plaintiffs is an individual consumer who made a Medicare Part B co-payment or a supplemental Medicare insurer. Plaintiffs assert in their reply brief that the association plaintiffs include individuals who made payments pursuant to Part B, yet have not established that assertion.<sup>14</sup> Even if an association member made a Part B co-

class. In contrast, several of the cases relied upon by plaintiffs are settlement classes (Plfs.' Reply Mem. at 24 n.74), where the courts did not face the difficulty of attempting to instruct a jury on multiple state laws. As the Third Circuit stated in *Warfarin*, with respect to state law variations, the difference between a settlement class and litigation class "is key." *See In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 529 (3d Cir. 2004). Moreover, despite the few isolated exceptions cited by plaintiffs, it is clear that most courts refuse to certify nationwide class actions when varying state laws must be applied. *See* Appendix C, attached hereto.

<sup>&</sup>lt;sup>14</sup> For example, CCJ's witness admitted at her deposition that the assertion in her affidavit was without support. (Townsend (CCJ) Apr. 20, 2004 Dep. Tr. 179.) None of the association affidavits identifies any specific members who made a Part B payment for any of the drugs at issue here. Indeed, this Court previously dismissed the claims of the association claimants for failure to identify any member who had suffered an injury. See In re Pharmaceutical Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172, 194 (D. Mass. 2003).

payment, the association cannot sue for damages on his or her behalf. *See Warth v. Seldin*, 422 U.S. 490, 515-16 (1975). Since the association plaintiffs are not eligible for money damages, their legal interest in the outcome of this litigation is insufficient to satisfy the typicality requirement. *See Rosmer v. Pfizer*, *Inc.*, No. Civ. A. 9:99-2280-18RB. 2001 WL 34010613, \*5 (D.S.C. Mar. 30, 2001).

The claim of UCFW is also subject to unique circumstances that render it atypical and inadequate to represent the class. When UCFW reimburses for drugs covered under Medicare Part B, the "allowed amount" paid to the physician is governed by the terms of a privately negotiated contract with

not the Medicare statute. Thus, in the few cases where UFCW pays REDACTED

"secondary" to Medicare, UFCW pays the difference between the contractual allowance REDACTED

and any payments made by Medicare. 15 As a result, where the total allowance is less than the total Medicare allowance, UFCW's payment is less than the 20% Medicare co-payment. Thus, UCFW's claim depends on all of the same individual issues that permeate private reimbursement contracts discussed in supra at section II.A. 16

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#### REDACTED

Recognizing the deficiencies in their proposed class representatives, plaintiffs now propose – after this litigation has been pending for over three years – that they be permitted to add two new class representatives. But this Court has stated that it will entertain no further amendments: "I'm not allowing any amendments that add dramatically new claims." (Tr. of Nov. 21, 2004 Hearing Before Hon. Patti B. Saris at 46.) Even if plaintiffs were allowed to amend the complaint again to bring in these new entities, defendants have not had an opportunity to conduct discovery regarding these two newly proposed class representatives. This Court should not accept their naked, self-serving affidavits as evidence of typicality or adequacy.

# III. PLAINTIFFS' PROPOSED CLASSES FAIL THE SUPERIORITY REQUIREMENT OF RULE 23(b)(3)

Plaintiffs' reply brief fails to provide answers to the numerous concerns defendants have identified in their proposed Trial Plan. First, plaintiffs do not dispute that under that Trial Plan no class representatives or individual class members will offer testimony during the Phase I "liability" determination nor will they be subject to cross-examination. Fundamental fairness and due process mandate that defendants have the right to confront their adversaries *before* a jury renders a verdict on any ultimate issue. Second, plaintiffs do not dispute that Phase I will involve little more than Dr. Hartman attempting to demonstrate whether defendants' alleged conduct *could* cause injury (*i.e.*, general causation), rather than whether it *did* cause injury (*i.e.*, specific causation). The latter determinations will apparently be reserved for the vague (but potentially endless) Phase II proceedings. (Hartman Oct. 7, 2004 & Oct. 8, 2004 Dep. Trs. 162-63, 221-22, 227-29, 335-36, 338-39, 359-60.) Such a procedure, which ignores the need for proof of individual causation as to each claim and each defendant, is legally defective. *See Piggly Wiggly Clarksville, Inc. v. Interstate Brands Corp.*, 215 F.R.D. 523, 531 (E.D. Tex. 2003) *aff'd*, 2004 WL 1245275 (5th Cir. June 7, 2004).

Plaintiffs' proposal to spread causation determinations over two phases also raises an intolerable risk that a second jury will reconsider the findings of the first, in violation of the Seventh Amendment. Other issues that implicate Seventh Amendment concerns if left to separate juries include the determination of comparative and third party fault in states where such issues are relevant to whether violation of a consumer protection statute has occurred. See, e.g., Loughridge v. Goodyear Tire and Rubber Co., 207 F. Supp. 2d 1187, 1191 (D. Colo. 2002); Gennari v. Weichert Co. Realtors, 691 A.2d 350, 367 (N.J. 1997); Southwest Bank v. Info. Support Concepts, Inc., 149 S.W.3d 104, 107 n.7 (Tex. 2004).

Plaintiffs' elaboration of their trial plan in their reply brief only magnifies its flaws. For instance, plaintiffs suggest that the Phase I jury will answer interrogatories as to the reasonableness of the spread for each NDC at issue. (Plfs.' Reply Mem. 25; Hartman Rebuttal

Decl. ¶ 15(a) n.6.) Yet, asking a single jury to engage in that endeavor for 136 products (and over 1,000 NDCs) raises intractable manageability problems.<sup>17</sup> The AWP for each NDC typically changes at least once annually. Even if a jury were able to answer the interrogatories on the reasonableness of the spread for the over 1,000 NDCs and AWPs for a single year during the 14-year class period, separate interrogatories will be necessary for each of the six named plaintiff funds to determine whether any of the named plaintiffs actually paid for any of the NDCs at issue and, if so, which NDC, and at which point in time during the Class Period. The number of special interrogatories to be answered by a single jury on this issue alone therefore quickly escalates to over 6,000.

Moreover, in order for the jury's findings on potentially "common" elements to have any applicability to the claims of the absent class members, the jury cannot render a generic liability verdict, but must submit specific findings as to each element of each of plaintiffs' causes of action in relation to each act, transaction, product and time period at issue. *See Blyden v. Mancusi*, 186 F.3d 252, 271 (2d Cir. 1999) (reversing jury verdict because the verdict form contained general findings of liability that were useless in determining defendants' liability to any specific class member). <sup>18</sup>

Plaintiffs' proposal for a vague, bifurcated proceeding does not cure the preceding manageability concerns. In numerous cases, courts have noted that the bifurcation of a trial into liability and damage phases does not mitigate or alleviate manageability problems. *See, e.g.*, *White v. Williams*, 208 F.R.D. 123, 133 (D.N.J. 2002); *Jones v. Allercare, Inc.*, 203 F.R.D. 290,

<sup>&</sup>lt;sup>17</sup> As plaintiffs' expert notes in his rebuttal declaration, "[a]ny particular drug may be characterized by as many as 30 NDCs, which are differentiated by presentation (e.g., strength, package size, number of prescribed doses per day, form (capsule, tablet, IV)). At any point in time, a single unique AWP exists for each and every NDC of each drug." (Hartman Rebuttal Decl. ¶ 15(a) n.6.)

<sup>&</sup>lt;sup>18</sup> Plaintiffs' sole effort to distinguish *Blyden* is by noting in a parenthetical that it was a § 1983 case arising from alleged prison beatings following a riot. Because *Blyden* concerned a single cause of action arising out of single event, *Blyden* was far more manageable than this case, where plaintiffs put at issue and assert both federal and 52 state law claims as to 136 products over a fourteen year time period.

307-08 (N.D. Ohio 2001); In re Ford Motor Co. Ignition Switch Prods. Liab. Litig., 194 F.R.D. 484, 495 (D.N.J. 2000). Indeed, in one of the cases cited by plaintiffs, the court rejected plaintiffs' bifurcated trial plan. See Chisolm v. TranSouth Fin. Corp., 194 F.R.D. 538, 553 (E.D. Va. 2000). Even at the rate of ten plaintiffs a day, it would take nearly four years of judicial (and jury) time to resolve individual issues such as causation, reliance, injury, statute of limitations, comparative fault, failure to mitigate, and damages for just 10,000 class members.

Plaintiffs rely primarily on *Smilow v. Southwestern Bell Mobile Sys., Inc.*, 323 F.3d 32 (1st Cir. 2003), as support for their argument that individual damage phases would be manageable. *Smilow* turned on the interpretation of a form contract and the court found that individual factual determinations could be "accomplished using computer records, clerical assistance and objective criteria – thus rendering unnecessary an evidentiary hearing on each claim." *Id.* at 40. Plaintiffs argued that breach, causation, and damages could all be established using a mechanical process based on the defendant's own telephone billing records. *Id.* at 40-41. In contrast, the record evidence here is that any determination as to whether the "spread" of a specific NDC exceeded Dr. Hartman's "expectations yardstick" or whether a physician's reimbursements were based upon AWP, will require a transaction-by-transaction determination. (Young Sur-Rebuttal Decl. at ¶¶ 79-81).

Plaintiffs' suggestion that the Court may use Fed. R. Civ. P. 23(c)(4) to certify certain issues fails. Rule 23(c)(4) is only a component of, and not a trump card to, Rule 23. See Castano v. American Tobacco Co., 84 F.3d 734, 745 n. 21 (5th Cir. 1996) ("proper interpretation of the interaction between subdivisions (b)(3) and (c)(4) is that a cause of action, as a whole, must satisfy the predominance requirement of (b)(3) and that (c)(4) is a housekeeping rule that allows courts to sever the common issues for a class trial.").

# IV. THE CASES ON WHICH PLAINTIFFS RELY ARE VERY DIFFERENT FROM THIS CASE

Plaintiffs assert that there is a trend in "recent consumer and commercial class actions that . . . serve as paradigms for the Court to follow." (Plfs.' Reply Mem. at 24 & 24 n.77; see also id. at 2-3) Plaintiffs cite these cases in support of both their predominance and superiority arguments. On examination, however, those cases are very different from this one.

Plaintiffs begin holding out the recent decision in *In re Initial Pub. Offering Sec. Litig.* ("*In re IPO*"), 2004 U.S. Dist. Lexis 20497 (S.D.N.Y., Oct. 13, 2004), as a "landmark" that reveals all this Court needs to know about Rule 23. In fact, *In re IPO* is a securities class action, and the court's entire discussion of predominance was based on doctrines peculiar to such cases, *see id.* at \*129-175, including most notably the "fraud on the market theory," which is applicable only to "efficient markets." *See id.* at \*134-135. These doctrines have no applicability to this case, for even Dr. Hartman admits that the market for pharmaceuticals is not an efficient one. (Hartman Oct. 7, 2004 Dep. Tr. at 115.)

Plaintiffs also rely on consumer fraud cases that can be characterized, in Judge Posner's phrase, as "uniform misrepresentation" cases. *Carnegie v. Household Int'l, Inc.*, 376 F.3d 656, 662 (7th Cir. 2004). Such cases typically involve claims of consumer finance fraud that feature form contracts for loans, credit card services and the like that are offered to the general public without any individual negotiations. These cases are frequently certified for class treatment because the instruments of the alleged fraud apply uniformly to all class members. However, when the negotiation and formation of the contract is individualized, as here, such cases are not appropriate for certification. *See supra* discussion at I.A. (citing cases).

Plaintiffs further rely on antitrust cases, where class certification is found to be appropriate because proof of a defendant's antitrust violation does not require the participation of plaintiffs. See In re Visa Check/MasterMoney Antitrust Litig., 280 F.3d 124 (2d Cir. 2001). This

<sup>&</sup>lt;sup>19</sup> In addition to *Carnegie*, other cases relied upon by plaintiffs also fall within this category. *See Chisolm*, 194 F.R.D. at 538; *Weil v. Long Island Savings Bank*, 200 F.R.D. 164 (E.D.N.Y. 2001).

group includes cases involving pharmaceutical companies that were alleged to have acted in various ways to suppress generic competition.<sup>20</sup> These cases, too, do not require examination of the plaintiff to determine a defendant's liability.

Finally, plaintiffs rely on Klay v. Humana, Inc., 382 F.3d 1241 (11th Cir. 2004). That case upheld certification of a class of doctors who alleged that they were victims of a nationwide conspiracy and a vast RICO enterprise that included nearly all the major HMOs in the country. The court found that the common issues of fact involved in proving this conspiracy and the enterprise were "quite substantial" and "would tend to predominate over all but the most complex individualized issues." Id. at 1258-59. This case, by contrast, does not involve such a large conspiracy and enterprise. Rather than a nationwide combination of all HMOs, the conspiracies and enterprises alleged here are bilateral – they are alleged to exist between each defendant and each of the three major PBMs. Thus, plaintiffs' conspiracy/enterprise allegations are defendant-specific and do not bulk as large as the nationwide conspiracy/enterprise allegations in Klay, which linked the entire health insurance industry together. Furthermore, plaintiffs' "expectations" theory and the multiplicity of contracts involved in this case will require a high level of participation by each class member in proving liability. The Klay decision, therefore, has no bearing on this case.

#### CONCLUSION

For all of the foregoing reasons, plaintiffs' Motion for Class Certification should be DENIED.

<sup>&</sup>lt;sup>20</sup> See In re Terazosin Hydrochloride Antitrust Litig., 203 F.R.D. 551 (S.D. Fla. 2001); In re Synthroid Mktg. Litig., 188 F.R.D. 295 (N.D. Ill. 1999). Plaintiffs' reliance on Terazosin is misplaced, as it was vacated and remanded, see Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 350 F.3d 1181 (11th Cir. 2003), a fact plaintiffs neglect to point out.

### Respectfully submitted,

### THE TRACK ONE DEFENDANTS

By: /s/Jessica V. Barnett

Nicholas C. Theodorou (BBO #496730) Jessica V. Barnett (BBO # 650535) Foley Hoag LLP 155 Seaport Boulevard Boston, MA 02110

D. Scott Wise Michael Flynn Kimberley Harris Davis Polk & Wardwell 450 Lexington Avenue New York, NY 10017

Attorneys for AstraZeneca Pharmaceuticals LP

Steven M. Edwards Lyndon M. Tretter Hogan & Hartson, LLP 875 Third Avenue New York, NY 10022

Attorneys for the Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp. and Apothecon, Inc.

Mark H. Lynch Covington & Burling 1201 Pennsylvania Avenue, N.W. Washington, DC 20004-7566

Frederick G. Herold Dechert LLP 975 Page Mill Road Palo Alto, CA 94304-1013

Geoffrey E. Hobart Holland & Knight LLP 10 St. James Ave. Boston, MA 02116

Attorneys for SmithKlineBeecham Corp. d/b/a GlaxoSmithKline

William F. Cavanaugh, Jr. Andrew D. Schau Erik Haas Patterson, Belknap, Webb & Tyler LLP 1133 Avenue of the Americas New York, NY 10036 6710

Attorneys for the Johnson and Johnson Defendants

John T. Montgomery Brien T. O'Conor Steven A. Kaufman Darcy W. Shearer Eric P. Christofferson Ropes & Gray LLP One International Place Boston, MA 02110

Attorneys for Schering-Plough Corp. and Warrick Pharmaceuticals Corp.

Dated: February 4, 2005

### **CERTIFICATE OF SERVICE**

I hereby certify that on February 4, 2005, I caused a true and correct copy of the foregoing Track One Defendants' Sur-reply in Opposition to Class Certification [REDACTED VERSION FOR PUBLIC FILING] and the accompanying Declaration of Carlos M. Pelayo to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2.

\_\_/s/ Jessica V. Barnett
Jessica V. Barnett

# APPENDIX C CASES DENYING CERTIFICATION OF NATIONWIDE CLASS ACTIONS

In re Bridgestone/Firestone, Inc., Tires Prods. Liab. Litig., 288 F.3d 1012, 1015-1019 (7th Cir. 2002) (included consumer protection act claim)

Stirman v. Exxon Corp., 280 F.3d 554, 563-66 (5th Cir. 2002)

Zinser v. Accufix Research Inst., Inc., 253 F.3d 1180, 1187-88, amended, 273 F.3d 1266 (9th Cir. 2001)

Szabo v. Bridgeport Machs., Inc., 249 F.3d 672, 678 (7th Cir. 2001)

In re LifeUSA Holding Inc., 242 F.3d 136, 147 (3d Cir. 2001)

Spence v. Glock, 227 F.3d 308, 310-16 (5th Cir. 2000)

Andrews v. AT&T, 95 F.3d 1014, 1024 (11th Cir. 1996)

Castano v. Am. Tobacco Co., 84 F.3d 734, 741-44 (5th Cir. 1996)

Georgine v. Amchem Prods., Inc., 83 F.3d 610, 617-18 (3d Cir. 1996), aff'd sub nom. Amchem Prods., Inc. v. Windsor, 521 U.S. 591 (1997)

In re Am. Med. Sys., Inc., 75 F.3d 1069, 1085-86, (6th Cir. 1996)

In re Rhone-Poulenc Rorer Inc., 51 F.3d 1293, 1302 (7th Cir. 1995)

Walsh v. Ford Motor Co., 807 F.2d 1000, 1011-17 (D.C. Cir. 1986)

In re N. Dist. of Cal., Dalkon Shield IUD Prods. Liab. Litig., 693 F.2d 847, 850 (9th Cir. 1982)

Bowers v. Jefferson Pilot Fin. Ins. Co., 219 F.R.D. 578, 580-84 (E.D. Mich. 2004)

*In re Baycol Prods. Litig.*, 218 F.R.D. 197, 207-08, 214-16 (D. Minn. 2003)

Dawson v. Dovenmuehle Mortgage, Inc., 214 F.R.D. 196, 201 (E.D. Pa. 2003) (included consumer protection act claim)

Auscape Int'l v. Nat'l Geographic Soc'y, No. 02 Civ. 6441 LAK HBP, 2003 WL 23531750, at \*14-16 (S.D.N.Y. July 25, 2003) (included consumer protection act claim)

Gyarmathy & Assocs., inc. v. TIG Ins. Co., No. Civ. A. 3:02-CV-1245, 2003 WL 21339279, at \*2 (N.D. Tex. June 3, 2003)

In re Paxil Litig., 212 F.R.D. 539, 544-45 (C.D. Cal. 2003)

Nudell v. Burlington N. & Santa Fe Ry. Co., No. A3-01-41, 2002 WL 1543725, at \*6 (D.N.D. July 11, 2002)

Lilly v. Ford Motor Co., No. 00 C 7372, 2002 WL 507126, at \*2-3 (N.D. III. Apr. 3, 2002)

Lewis Tree Serv., Inc. v. Lucent Techs. Inc., 211 F.R.D. 228, 233, 235-37 (S.D.N.Y. 2002) (included consumer protection act claim)

In re Rezulin Prods. Liab. Litig., 210 F.R.D. 61, 70-71 (S.D.N.Y. 2002) (included consumer protection act claim)

Montgomery v. New Piper Aircraft, Inc., 209 F.R.D. 221, 227-30 (S.D. Fla. 2002) (included consumer protection act claim)

Lewallen v. Medtronic USA, Inc., No. C 01-20395 RMW, 2002 WL 31300899, at \*5 (N.D. Cal. Aug. 28, 2002)

In re Propulsid Prods. Liab. Litig., 208 F.R.D. 133, 146-47 (E.D. La. 2002)

Block v. Abbott Labs., No. 99 C 7457, 2002 WL 485364, at \*5-6 (N.D. Ill. Mar. 29, 2002) (included consumer protection act claim)

In re Citigroup, Inc., No. CIV.A.10011912REK, 2001 WL 1682865, at \*3 (D. Mass. Dec. 19, 2001)

Rosmer v. Pfizer, Inc., No. CIV. A. 9:99-2280-18RB, 2001 WL 34010613, at \*5 (D.S.C. Mar. 30, 2001)

Hammett v. Am. Bankers Ins. Co., 203 F.R.D. 690, 700-02 (S.D. Fla. 2001)

Duncan v. N.W. Airlines, Inc., 203 F.R.D. 601, 613-14 (W.D. Wash. 2001)

Renton v. Kaiser Found. Health Plan, Inc., No. C00-5370RJB, 2001 WL 1218773, at \*3-5 (W.D. Wash. Sept. 24, 2001)

Neely v. Ethicon, Inc., No. 1:00-CV-00569, 2001 WL 1090204, at \*5-9 (E.D. Tex. Aug. 15, 2001)

Oxford v. Williams Cos., 137 F. Supp. 2d 756, 764 (E.D. Tex. 2001)

Jones v. Allercare, Inc., 203 F.R.D. 290, 307 n.8 (N.D. Ohio 2001)

Stipelcovich v. Directv, Inc., 129 F. Supp. 2d 989, 994-95 (E.D. Tex. 2001) (included consumer protection act claim)

Zapka v. Coca-Cola Co., No. 99 CV 8238, 2000 WL 1644539, at \*4 (N.D. Ill. Oct. 27, 2000) (included consumer protection act claim)

Yadlosky v. Grant Thornton L.L.P., 197 F.R.D. 292, 300-01 (E.D. Mich. 2000)

Hallaba v. Worldcom Network Servs. Inc., 196 F.R.D. 630, 637-41 (N.D. Okla. 2000)

In re Ford Motor Co. Ignition Switch Prods. Liab. Litig., 194 F.R.D. 484, 488-90 (D.N.J. 2000) (included consumer protection act claim)

Lyon v. Caterpillar, Inc., 194 F.R.D. 206, 211-221 (E.D. Pa. 2000) (included consumer protection act claim)

Adams v. Kansas City Life Ins. Co., 192 F.R.D. 274, 277-78 (W.D. Mo. 2000)

Potchin v. Prudential Home Mortgage Co., No. 97-CV-525 (CBA), 1999 WL 1814612, at \*10 (E.D.N.Y. Nov. 12, 1999) (included consumer protection act claim)

Cunningham v. PFL Life Ins. Co., No. C 98-67 MJM, 1999 WL 33656879, at \*5-6 (N.D. Iowa Aug. 25, 1999)

Velasquez v. Crown Life Ins. Co., Nos. CIV. No. M-97-064, MDL 1096, 1999 WL 33305652, at \*3-6 (S.D. Tex. Aug. 10, 1999)

Carpenter v. BMW of N. Am., Inc., No. Civ. A. 99-CV-214, 1999 WL 415390, at \*2-3 (E.D. Pa. June 21, 1999) (included consumer protection act claims)

Chilton Water Auth. v. Shell Oil Co., No. CIV.A. 98-T-1452-N, 1999 WL 1628000, at \*5-8 (M.D. Ala. May 21, 1999)

Schwartz v. Upper Deck Co., 183 F.R.D. 672, 677-79 (S.D. Cal. 1999)

Rothwell v. Chubb Life Ins. Co. of Am., 191 F.R.D. 25, 33 n. 7 (D.N.H. 1998)

Clay v. Am. Tobacco Co., 188 F.R.D. 483, 495-99 (S.D. Ill. 1999) (included conspiracy and consumer protection act claims)

Kaczmarek v. IBM Corp., 186 F.R.D. 307, 312-13 (S.D.N.Y. 1999) (included consumer protection act claim)

Dhamer v. Bristol-Myers Squibb Co., 183 F.R.D. 520, 530-34 (N.D. Ill. 1998)

In re Jackson Nat'l Life Ins. Co. Premium Litig., 183 F.R.D. 217, 222-24 (W.D. Mich. 1998)

Dubose v. First Sec. Sav. Bank. 183 F.R.D. 583, 587-88 (M.D. Ala. 1997)

In re Ford Motor Co. Vehicle Paint Litig., 182 F.R.D. 214, 222-24 (E.D. La. 1998)

Chin v. Chrysler Corp., 182 F.R.D. 448, 457-62 (D.N.J. 1998)

Marascalco v. Int'l Computerized Orthokeratology Soc'y, Inc., 181 F.R.D. 331, 337-41 (N.D. Miss. 1998)

Fisher v. Bristol-Myers Squibb Co., 181 F.R.D. 365, 368-72 (N.D. Ill. 1998)

Borskey v. Medtronics, No. CIV. A. 94-2302, 1998 WL 122602, at \*3 (E.D. La. Mar. 18, 1998)

Poe v. Sears, Roebuck & Co., No. Civ. A1:96-CV-358-RLV, 1998 WL 113561, at \*2-4 (N.D. Ga. Feb. 13, 1998)

In re Ford Motor Co. Bronco II Prod. Liab. Litig., 177 F.R.D. 360, 368-72 (E.D. La. 1997)

Peoples v. Am. Fidelity Life Ins. Co., 176 F.R.D. 637, 642-43 (N.D. Fla. 1998)

Clement v. Am. Honda Fin. Corp., 176 F.R.D. 15, 22-23 & nn. 10-12 (D. Conn. 1997) (included consumer protection act claim)

In re Stucco Litig., 175 F.R.D. 210, 215-17 (E.D.N.C. 1997) (included consumer protection act claim)

Mack v. Gen. Motors Acceptance Corp., 169 F.R.D. 671, 677-78 (M.D. Ala. 1996)

Ilhardt v. A.O. Smith Corp., 168 F.R.D. 613, 619-20 (S.D. Ohio 1996)

Harding v. Tambrands Inc., 165 F.R.D. 623, 629-32 (D. Kan. 1996) (included consumer protection act claim)

McBride v. Galaxy Carpet Mills, Inc., 920 F. Supp. 1278, 1284-86 (N.D. Ga. 1995)

Kurczi v. Eli Lilly & Co., 160 F.R.D. 667, 673-74 (N.D. Ohio 1995)

Barbarin v. Gen. Motors Corp., No. CIV.A. 84-0888, 1993 WL 765821, at \*3 (D.D.C. Sept. 22, 1993)

Abbent v. Eastman Kodak Co., No. 90CV3436, 1992 WL 1472751, at \*6-7 (D.N.J. Aug. 28, 1992)

Truckway, Inc. v. Gen. Elec., No. 91-0122, 1992 WL 70575, at \*7 (E.D. Pa. Mar. 30, 1992) (included consumer protection act claim)

In re Masonite Corp. Hardboard Siding Prods. Liab. Litig., 170 F.R.D. 417, 421-24 (E.D. La. 1997)

Matjastic v. Quantum Pharmics, Ltd., No. 90-0647, 1991 WL 238304, at \*6 (E.D. Pa. July 22, 1991) (included consumer protection act claim)

Rave v. Medtronic Corp., 696 F. Supp. 1273, 1275 (D. Minn. 1988)

Ikonen v. Hartz Mountain Corp., 122 F.R.D. 258, 265 (S.D. Cal. 1988)

Feinstein v. Firestone Tire & Rubber Co., 535 F. Supp. 595, 605-06 (S.D.N.Y. 1982)

Lewis v. Exxon Corp., 725 So. 2d 930, 932-33 (Ala. 1998) (included consumer protection act claim)

Kilpatrick v. Green Tree Fin. Corp., 723 So. 2d 6, 9-10 (Ala. 1998) (included consumer protection act claim)

Frelin v. Oakwood Homes Corp., No. CIV-2001-53-3, 2002 WL 31863487, at \*11-13 (Ark. Cir. Ct. Nov. 25, 2002)

Canon U.S.A., Inc. v. Super. Ct., 79 Cal. Rptr. 2d 897, 901-02 (Ct. App. 1998)

Hutson v. Rexall Sundown, Inc., 837 So. 2d 1090, 1093-95 (Fla. Dist. Ct. App. 2003) (included consumer protection act claim)

Gilman v. John Hancock Variable Life Ins. Co., No. 02-0051, 2003 WL 23191098, at \*11-15 (Fla. Cir. Ct. Oct. 20, 2003)

Dragon v. Vanguard Indus., Inc., 89 P.3d 908, 914-19 (Kan. 2004)

Carr v. GAF, Inc., 711 So. 2d 802, 807 (La. Ct. App. 1998) (included conspiracy to defraud claim)

Philip Morris Inc. v. Angeletti, 752 A.2d 200, 230-32 (Md. 2000) (included consumer protection act and conspiracy to defraud claims)

Snell v. Geico Corp., No. Civ. 202160, 2001 WL 1085237, at \*8-10 (Md. Cir. Ct. Aug. 14, 2001)

Sieglock v. Burlington N. Santa Fe Ry. Co., 81 P.3d 495, 498-99 (Mont. 2003)

Carroll v. Cellco P'ship, 713 A.2d 509, 513-14, 518 (N.J. Super. Ct. App. Div. 1998) (included consumer protection act claim)

Fink v. Ricoh Corp., 839 A.2d 942, 973-91 (N.J. Super. Ct. Law Div. 2003) (included consumer protection act claim)

Duvall v. TRW, Inc., 578 N.E.2d 556, 559-61 (Ohio Ct. App. 1991)

Debbs v. Chrysler Corp., 810 A.2d 137, 158-59 (Pa. Super. Ct. 2002) (included consumer protection act claim)

Lewis v. Bayer AG, No. 002353, 2004 WL 1146692, at \*10-13 (Pa. Ct. Com. Pl. Nov. 8, 2004) (included consumer protection act claim)

Zarella v. Minn. Mut. Life Ins. Co., No. CIV A 96-2782, 1999 WL 226223, at \*9 (R.I. Super. Ct. Apr. 14, 1999)

Compag Computer Corp. v. Lapray, 135 S.W.3d 657, 671-81 (Tex. 2004)

Henry Schein, Inc. v. Stromboe, 102 S.W.3d 675, 695-99 (Tex. 2002) (included consumer protection act claim)